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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,738	01/02/2001	Geng Zhang	970663.CIP	3767

23595 7590 01/28/2003

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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
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3762

8

DATE MAILED: 01/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/753,738

Applicant(s)

ZHANG ET AL. *HCT*

Examiner

Kennedy Schaetzle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11-8-02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 3-10, 13, 15, 16, 19-23, 26-30 and 33-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 11, 12, 17, 18, 24, 25, 31, 32 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 January 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 6) ☐ Other:

DETAILED ACTION***Election/Restrictions***

1. Applicant's election with traverse of species number one (the species involving sensing of the evoked potential between an atrial ring electrode and a ventricular ring electrode) in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the requirement is "...outrageous and totally unwarranted; and, if maintained, the ruling fragments this application into a state that puts such an undue burden on the applicants that, in effect, it prevents them from realizing the efforts of their invention." This is not found persuasive because conclusory statements will have no effect in overcoming this requirement. The litmus test of determining whether or not a proper restriction exists is *not* whether the applicant would be burdened, but rather whether the *examiner* would be burdened (see MPEP section 803). With this in mind, it is unclear how the applicant can state that on the one hand, the division of the invention into such a large number of different species is unreasonable to the point of being outrageous, while on the other hand, consider such an outrageously large number of species to be a reasonable number for the purposes of examination. Furthermore, contrary to the applicants' assertion that they would be prevented from realizing the efforts of their invention if such a restriction were upheld, as stated in the previous Office Action, upon the allowance of a generic claim, the applicants would be entitled to consideration of claims to additional species as set forth in 37 CFR 1.141. The requirement is still deemed proper and is therefore made FINAL.

2. Regarding claim 42, in order for a claim to be considered generic it must by definition be generic to *all* the species (see MPEP section 806.04(d) for a definition of a generic claim). Claim 42 is clearly not a generic claim since it contains limitations not present in all of the species. The requirement that the evoked response be detected between at least one atrial electrode and at least one ventricular electrode is not found in a variety of different species such as those utilizing a can electrode or a superior vena cava electrode.

3. It is noted that the applicant has included claim 3 in the list of claims reading on the elected species. Claim 3 is not however drawn to the elected species involving

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sensing of the evoked potential between an atrial ring electrode and a ventricular ring electrode. As such, claim 3 will be considered withdrawn from consideration.

Drawings

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the system showing an atrial lead with a ventricular tip electrode in combination with a ventricular lead (claim 17) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: there does not appear to be antecedent basis for a system which has both atrial and ventricular leads, wherein the atrial lead has a ventricular tip electrode (note claim 17).

6. The disclosure is objected to because of the following informalities: the continuing data listed on page 1 of the specification must be updated to reflect the current status of the cited applications.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 17^{and 18} are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 17, the reference to the atrial lead as having a ventricular tip electrode is confusing considering that one would assume an atrial lead is to be contained in the

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atrium and therefore not contain a ventricular electrode. In light of the drawings, the examiner will assume it was the applicants' intent to recite that the atrial lead includes an *atrial* tip electrode when considering the merits of the claim.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 2, 11, 12, 14, 17, 18, 24, 25, 31, 32 and 42 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Greeninger et al. (Pat. No. 5,324,310).

Claims 1, 2, 11, 12, 14, 18, 24, 25, 31, 32 and 42 are clearly anticipated.

In re claim 17, note the above rejection under 35 U.S.C. §112, 2nd paragraph.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

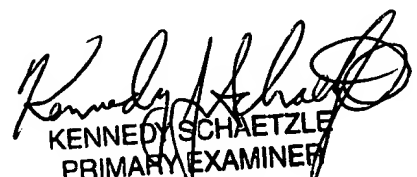
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is (703) 308-2211. The examiner can normally be reached on M-F from 9:30 - 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

KJS

January 22, 2003


KENNEDY SCHAETZLE
PRIMARY EXAMINER
1-22-03